UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATE OF NEW JERSEY, ex rel. STEVE GREENFIELD, et al., Plaintiffs, v. MEDCO HEALTH SYSTEMS, INC., ACCREDO HEALTH GROUP, INC., and HEMOPHILIA HEALTH SERVICES, INC., Defendants.	CIVIL NO. 12-522(NLH)(AMD) **OPINION**

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HILLMAN, District Judge

In this *qui tam* action, plaintiff Steve Greenfield claims that defendants violated the federal False Claims Act, as well as twenty-four state and city statutes regulating false claims. Presently before the Court is the motion of defendants to dismiss plaintiff's complaint. For the reasons expressed below, defendants' motion will be granted, but plaintiff will be granted leave to re-file his claims should he choose to do so.

BACKGROUND

Greenfield filed his complaint against defendants Medco Health Systems, Inc., Accredo Health Group, Inc., and Hemophilia Health Services, Inc. ("HHS"),[1] pursuant to 31 U.S.C. §§ 3729 and 3720,[2]

[1]According to plaintiff's complaint, Medco provides pharmacy services to private and public employers, health plans, labor unions, government agencies, and those under Medicare Part D prescription drug plans; Accredo is a wholly owned subsidiary of Medco, and provides specialty pharmacy services to patients with complex conditions; and HHS is a subsidiary of Accredo, and it provides hemophilia therapy management programs in the United States.

[2]A private individual, otherwise known as a relator, may bring a civil action in the name of the United States to enforce § 3729 of the FCA and may share a percentage of any recovery resulting from the suit. U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 305 (3d Cir. 2011) (citing 31 U.S.C. § 3730(b) & (d)). Because it was filed as a *qui tam* action, the entire case was filed under seal in order to allow the United States and interested states to investigate whether they wished to intervene in the action and prosecute plaintiff's claims on their behalf. See 31 U.S.C. § 3730(b)(2). Neither the United States government nor any of the states listed in the complaint chose to intervene in the action. Accordingly, the complaint was unsealed, and from that point on the case has been publically accessible. Since the case was unsealed, plaintiff filed two

contending that defendants submitted false claims for payment from the United States, as well as payment from various states in violation of their false claim laws, because defendants falsely certified their compliance with the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) (referred herein as the Anti-Kickback statute, or "AKS").[3] Plaintiff contends that in his capacity as an area vice-president of Accredo, he learned of defendants' fraudulent practices related to their efforts to maintain and increase sales of their products to treat hemophilia.

As described in plaintiff's complaint, hemophilia is a rare bleeding disorder, and those with the disorder have little or no "clotting factor." Treatment for hemophilia is typically either "on-demand," where a patient receives factor replacement therapy to stop a bleed, or "prophylactic," where a patient receives factor replacement therapy to prevent a bleed. Clotting factor products are expensive, with the annual cost for the treatment of one patient ranging from $50,000 to $100,000 or more. As a result, New Jersey law requires health benefit providers to contract with

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amended complaints. It is plaintiff's second amended complaint that defendants are seeking to dismiss, referred to herein as "SAC."

[3]Plaintiff's opposition brief makes clear that he is not asserting an independent claim under the AKS, even though he lists it as a separate count in his complaint. (Pl. Opp. at 6.) The AKS is a criminal statute that does not provide for a private cause of action. If an entity falsely certifies its compliance with the AKS, that false certification can serve as a basis for a civil FCA violation. See 31 U.S.C. §§ 3729-3733.

state-authorized hemophilia home care providers to provide hemophilia patients with their necessary treatment regimen. There are four major state-authorized hemophilia providers in New Jersey, and Accredo is one of them.

The Hemophilia Association of New Jersey, Inc. ("HANJ") was created to coordinate and provide treatment to hemophilia patients. HANJ is a tax exempt entity that, through grants, funds referral entities and makes recommendations to the state for competitive providers. HANJ formed Hemophilia Services, Inc. ("HSI"), also a tax exempt organization, which works with treatment centers, insurers, and participating home care vendors to provide case management services for the hemophilia population in New Jersey. Essentially, HSI receives charitable donations, which it grants to HANJ, and HANJ provides insurance and other financial assistance to individuals with hemophilia.

According to plaintiff's complaint, Medco, through Accredo and HHS, made charitable contributions in the amount of $500,000 or more to HSI from 2007 through 2009, with the intent to buy influence and induce referrals to the defendants. Plaintiff claims that when defendants informed HANJ that their charitable contributions would be decreasing, HANJ's response demonstrated the quid quo pro arrangement between defendants' donations and HANJ's funneling of patients to defendants' products. For example, in October 2009, the director of HANJ, Elena Bostick, sent an email to Craig Mears, president of Accredo/HHS, explaining the ramifications

of the reduced funding, including the elimination of the $5,000 a month donation from Critical Care Services, a company which Accredo acquired in 2009. Bostick stated:

> 1. New Jersey has four HTC's--none of which has 340B designation.[4]
> 2. New Jersey has the lowest % of individuals with hemophilia on Medicaid.
> 3. New Jersey has enacted legislation which insures access to care, access to all hemophilia products, and to the providers of those products. This did not occur by accident.
> 4. HANJ's insurance Grant Program currently covers 65 individuals with hemophilia. 49 of these are your customers.
> 5. The State Dept. of Health reimburses less than 50% of the cost of the insurance Grant Program. The balance of this cost must be borne by HANJ/H.S.I.
> 6. Grants to NJ HTC's, for the fiscal year ended 6/30/09, exceeded $500,000. These dollars enabled our centers to continue to function despite shortfalls in government funding. It also alleviated the need for HTC's to explore 340B as a funding solution.

(SAC ¶ 79, Ex. P.) Bostick concluded that Accredo/HHS's elimination of Critical Care's pledge to HSI "seriously compromises the necessary level of funding required to continue to provide these services." (Id.)

Over the next year defendants allegedly discussed the business ramifications of their reduced contributions to HANJ/HSI on the sale of their hemophilia products. According to plaintiff's

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[4] "HTCs" are state-recognized hemophilia treatment centers. (SAC ¶ 68.) "340B designation" refers to the 340B Drug Pricing Program, which is a federal program that provides significant savings on outpatient drugs to qualified participants. (SAC ¶ 82, n.34.)

complaint, in a meeting in October 2010, Bostick again related HANJ's arrangement with defendants in which defendants would make donations to HANJ/HSI, which would in turn fund insurance for patients who used defendants' factor products. Patients with insurance plans funded by the charitable contributions of defendants would not be referred to any other competitor hemophilia product. (SAC ¶ 87.) If defendants reduced their contributions to HANJ/HSI, patients would be referred to competitors. (Id. ¶ 89.)

In March 2011, HSI president Jerry Seltzer sent a letter to its members, stating:

> As you are aware insurance costs continue to rise in the State of New Jersey. Over the past ten years a successful partnership between Hemophilia Services, Inc. (HSI), the State of New Jersey and the "authorized" home care providers, who participate in the HSI program, has been able to "subsidize" the cost of Insurance Policies for our "uninsured" patient population.
>
> Unfortunately, due to insufficient funding for this groundbreaking program, the ability for HSI to continue to support this program is now in jeopardy for the balance of 2011. One of our key providers (HHS/Accredo) has continued to significantly reduce its financial support for this program over the last two years. In the recent past, HSI, in cooperation with the Hemophilia Association of New Jersey (HANJ), and with a restructuring of the "patient criteria" for obtaining Insurance Policies, was able to absorb the additional cost no longer funded by HHS/Accredo. It should be noted that the cost to purchase Insurance Policies for our patient population in 2010, alone, approached one million dollars.
>
> However, I am writing at this time to advise you that, beginning January 2011, HHS/Accredo has chosen to reduce its financial support so significantly, that as a major participant, this reduction has placed the Insurance Program in jeopardy of being phased out, and ceasing to exist in the foreseeable future.
>
> If you are a client of HHS/Accredo or a participant in HSI's Insurance Program, on behalf of the HSI Board, I

> request that you IMMEDIATELY contact Craig Mears, President of HHS/Accredo. . . .
>
> It should be noted that if we do not receive a commitment from HHS/Accredo to restore financial support for the coming year (2011), "sadly" we will have to notify the State of NJ that the very successful Insurance Program for our uninsured patient population is in danger of being "phased out" due to lack of funds. . . .

(SAC ¶ 92, Ex. I-1.)

As a result of Seltzer's letter, approximately 75 Accredo/HHS clients expressed their concern over the funding cuts by sending letters to Accredo/HHS. Plaintiff claims that Accredo/HHS then began to analyze the loss of business they had already experienced, and could continue to experience in the future, due to HANJ/HSI's reaction to defendants' reduced donations. Defendants' business analysis questions included whether there was a quantifiable return on investment if they increased contributions from $175,000 to $350,000 and what was the likely business deterioration to the New Jersey market share if contributions were not increased. (SAC ¶ 96.) Based on this analysis, plaintiff contends that Accredo convinced Medco to restore funding to $350,000, with Mears explaining that when they reduced their contributions to HANJ/HSI, they saw a decline in business because HANJ/HSI wanted defendants to fund the insurance for patients using defendants' products. Of the 72 patients HSI provided insurance for, 58 were Accredo patients, and HANJ/HSI wanted Accredo to pay an equivalent amount. (Id. ¶ 98.) Plaintiff contends that Medco "found the additional money" to increase the donations so that they would not lose

business and maintain the referrals to their hemophilia products. (Id. ¶ 99, quoting Accredo vice-president Bruce Scott, "[O]kay, so we're at the point where they understand that we are willing to continue and willing to increase our contribution back to 350K and it is clear to them that we are not willing to contribute to an organization that is placing us in an unfavorable position with patients.").

Plaintiff claims that defendants knew that their arrangement with HANJ/HSI was an illegal kickback scheme, because the arrangement evidences defendants' control over a charity, the lack of independence between defendants and the charity, defendants' financial interest in the donations, and the connection between the donations and referrals, all of which violate the Anti-Kickback statute, as interpreted by the Office of Inspector General in its Advisory Opinion 10-19. (SAC ¶¶ 101-107.) Plaintiff contends that in addition to providing gifts, in the form of dinners, lunches, refrigerators, and equipment to patients that exceed the safe harbor amount ($10 per item/$50 limit per year), in order to influence the patient's continued use of Accredo,[5] this quid pro quo scheme between defendants and HANJ/HSI is a violation of the AKS, which has therefore caused defendants to falsely certify their

[5]Plaintiff claims that these gifts violate the Civil Monetary Penalty Law, 42 U.S.C. § 1320a-7(a), ("CMPL") because they improperly attempt to induce patients' choice of Medicare or Medicaid providers, and these gifts therefore violate the FCA. Plaintiff's claims concerning these excessive gifts are discussed in more detail below.

compliance with the AKS, a violation of the False Claims Act.

Defendants have moved to dismiss plaintiff's complaint in its entirety on several bases, including plaintiff's failure to comply with Rule 9(b) for his FCA claims, plaintiff's inability to link his allegations to any federally funded program, and plaintiff's lack of specificity as to Medco's actions. Defendants have also asked this Court to decline to continue exercising supplemental jurisdiction over plaintiff's state law claims. Plaintiff has opposed defendants' motion.[6]

DISCUSSION

A. Subject matter jurisdiction

This Court has jurisdiction over plaintiff's federal claims under 28 U.S.C. § 1331, and supplemental jurisdiction over plaintiff's state law claims under 28 U.S.C. § 1367.

B. Standard for Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. Evancho v. Fisher, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading

[6]Plaintiff has also filed a motion for leave to file a sur reply, which defendants have opposed. Because the Court has considered plaintiff's sur reply, as well as defendants' response to plaintiff's sur reply, the Court will therefore grant plaintiff's motion.

is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under the liberal federal pleading rules, it is not necessary to plead evidence, and it is not necessary to plead all the facts that serve as a basis for the claim. Bogosian v. Gulf Oil Corp., 562 F.2d 434, 446 (3d Cir. 1977). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." Baldwin Cnty. Welcome Ctr. v. Brown, 466 U.S. 147, 149-50 n.3 (1984) (quotation and citation omitted).

A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" Bell Atlantic v. Twombly, 550 U.S. 544, 563 n.8 (2007) (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Ashcroft v. Iqbal, 556 U.S. 662, 684 (2009) ("Our decision in Twombly expounded the pleading standard for 'all civil actions' . . . ."); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("Iqbal . . . provides the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before Twombly.").

Following the Twombly/Iqbal standard, the Third Circuit has instructed a two-part analysis in reviewing a complaint under Rule 12(b)(6). First, the factual and legal elements of a claim should

be separated; a district court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Fowler, 578 F.3d at 210 (citing Iqbal, 129 S. Ct. at 1950). Second, a district court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "'plausible claim for relief.'" Id. (quoting Iqbal, 129 S. Ct. at 1950). A complaint must do more than allege the plaintiff's entitlement to relief. Id.; see also Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (stating that the "Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element").

A court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has been presented. Hedges v. U.S., 404 F.3d 744, 750 (3d Cir. 2005) (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only

consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. S. Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd., 181 F.3d 410, 426 (3d Cir. 1999). A court may consider, however, "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). If any other matters outside the pleadings are presented to the court, and the court does not exclude those matters, a Rule 12(b)(6) motion will be treated as a summary judgment motion pursuant to Rule 56. Fed. R. Civ. P. 12(b).

C. Pleading standard under Fed. R. Civ. P. 9(b)

Because the SAC in this case alleges violations of the federal FCA, plaintiff's allegations with respect to these claims must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). Foglia v. Renal Ventures Management, LLC, 830 F. Supp. 2d 8, 13 (D.N.J. 2011) (citing United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998) (noting that Rule 9(b) "requires plaintiffs to plead fraud with particularity, specifying the time, place and substance of the defendant's alleged conduct[,]" and thus "provides sufficient deterrence against overly broad allegations" under the False Claims Act)). Accordingly, plaintiff must plead "with particularity the

circumstances constituting fraud[,]" but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The Third Circuit has held that "'Fed. R. Civ. P. 9(b) requires plaintiffs to plead the circumstances of the alleged fraud with particularity to ensure that defendants are placed on notice of the 'precise misconduct with which they are charged, and to safeguard defendants against spurious charges' of fraud.'" Foglia, 830 F. Supp. 2d at 13 (quoting Craftmatic Sec. Litig. v. Kraftsow, 890 F.2d 628, 645 (3d Cir. 1989)) (other citations omitted).

D. Analysis

As stated above, plaintiff claims that defendants' actions relating to their contributions to HANJ/HSI and excessive gifts to Medicare/Medicaid patients violate the False Claims Act, 31 U.S.C. § 3729(a)(1), (2), (3) (Counts One, Two, and Three).[7]

The primary purpose of the FCA[8] "is to indemnify the

[7]Counts Five through Twenty-Eight allege violations of the false claim acts of several states and cities.

[8]As explained in U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 303-304 (3d Cir. 2011), on May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub.L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA and re-designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B). The pre-FERA version of the FCA imposed liability on:

> [A]ny person who—
> (1) knowingly presents, or causes to be presented, to

government - through its restitutionary penalty provisions - against losses caused by a defendant's fraud." U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 303-304 (3d Cir. 2011) (quotations and citations omitted). In order to establish a prima facie FCA violation under section 3729(a)(1), a

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> an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)-(2).

The FCA as FERA has amended it, now imposes liability on:

> [A]ny person who— (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. § 3729(a)(1).

The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). For purposes of this case both versions of the FCA define a claim in pertinent part as a "request or demand ... for money or property that ... is presented to an officer, employee, or agent of the United States...." 31 U.S.C. § 3729(c) (pre-FERA); 31 U.S.C. § 3729(b)(2)(A)(I) (post-FERA). FERA contains a retroactivity provision which applies only to section 3729(a)(1)(B), and provides that that clause "take [s] effect as if enacted on June 7, 2008, and appl[ies] to all claims under [the FCA] that are pending on or after that date." Pub.L. No. 111-21 § 4(f)(1), 123 Stat. at 1625.

Even though plaintiff's complaint contains pre-FERA and post-FERA claims, the differences are not material to the Court's analysis.

plaintiff must prove that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." Id. at 304-05 (citations omitted).

There are two categories of false claims under the FCA: a factually false claim and a legally false claim. Id. (citation omitted). A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment. Id. Relatedly, falsely certifying compliance with the Anti-Kickback statute in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. U.S. ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009). Thus, to state a viable claim that defendants violated the AKS and, in turn, violated the FCA, the key allegation must be that defendants' alleged conduct is tied to payment from the United States government.[9]

Plaintiff argues that he has met his burden, under Rule 9(b),

[9]It is unclear whether plaintiff's FCA claims regarding excessive gifts are predicated on violations of the CMPL, and if they are, it is unclear whether such claims are viable. This issue is addressed below.

to show that defendants' improper charitable contributions and gifts to patients are tied to payment from the United States government: "[T]he facts plead in the Complaint show that the Defendants offer and give[] substantial inducements to HANJ/HSI that support hemophilia patients, disguised as 'charitable donations' when, in fact, such donations are prohibited 'remuneration' under the AKA because they are intended to induce referrals of hemophilia patients who receive benefits from Federal health care programs." (Pl. Opp. at 26.) To demonstrate that defendants' alleged "prohibited remuneration" is connected to patients who receive benefits from the federal government, plaintiff points to the following allegations in his complaint:

> The Complaint identifies and alleges that there were approximately 646 hemophilia patients in New Jersey as of the first quarter of 2011 and Defendant Hemophilia Health Services (HHS) had 401 of these individuals as active patients, or approximately 62% of the New Jersey Market [Complaint ¶ 71]. In addition, the Complaint also alleges and states that HANJ/HSI had 77 insurance recipients of which 59 were HHS clients [Complaint ¶ 83, Exhibit G-4]. Therefore, on the face of the Complaint itself, of the 401 HHS hemophilia patients, only 59 had private insurance, leaving the remaining 342 as part of the population that were beneficiaries of a Federal Health Care Program [Complaint ¶¶ 8, 9, 11, and 70].

(Pl. Opp. at 3.) Plaintiff also refers to Exhibit N to his complaint, which is a chart of Medco's hemophilia patients, listing the amount of factor each uses, each patient's insurer, and the "gift" provided to them, such as snacks, lunches and dinners. A few of these patients are listed as federal Medicare recipients.

The viability of plaintiff's claims regarding charitable donations and excessive gifts will be addressed separately.

1. Charitable contributions

Accepting as true that defendants' charitable contributions to HANJ/HSI were intended to induce referrals to defendants' hemophilia treatment products, and that defendants' actions demonstrated prohibited control over the charity's use of its donations, the facts pleaded in plaintiff's complaint are not sufficient, under his Rule 9(b) burden, to show that any of those contributions are tied to federal funds. To the contrary, the quid pro quo scheme between HANJ/HSI and defendants alleged by plaintiff appear to demonstrate that defendants' contributions were used by HANJ/HSI to avoid the need to avail themselves of any federal benefits program.

The heads of HANJ and HSI both tied defendants' contributions to their ability to fund private insurance programs for hemophilia patients. Elena Bostick pointed out that defendants' grants "alleviated the need for HTC's to explore 340B [the federal drug benefit program] as a funding solution." (SAC ¶ 79, Ex. P.) Similarly, Jerry Seltzer noted that without defendants' contributions, HSI's privately funded insurance program would be "phased out." (SAC ¶ 92, Ex. I-1.) Indeed, according to the claims in plaintiff's complaint, HANJ and HSI were so dependent on the contributions from defendants to pay the private insurance

premiums for their members that they practically extorted defendants into continuing their contributions by essentially blacklisting defendants and instituting a negative letter writing campaign.

Defendants' own cost-benefit analysis of whether to maintain their contributions to HANJ/HSI, as pleaded in plaintiff's complaint, also demonstrates that avoidance of the use of any federal benefits source was defendants' goal as well. When analyzing the "likely business deterioration to NJ market share if we don't increase" their charitable donations to HANJ/HSI, the data showed that "NJ HTC's will resort to developing 340B programs placing all new and existing business at risk. For any patient that switches to a 340B program, we will lose 100% of the margin associated with that patient unless we are able to service the 340B program, in which case we will lose approximately 50% to 60% of the margin . . . ." (SAC ¶ 96.) This analysis shows that it would be in defendants' best interests to steer clear of any federal funding program.

Contrary to plaintiff's argument, the data included in plaintiff's complaint does not assist in demonstrating a tie between defendants' contributions and the use of federal funds. The complaint states that in 2011, 59 of 401 hemophilia patients using defendants' products had private insurance provided by HANJ/HSI. Plaintiff claims that the remaining 352 patients using

defendants' products must therefore be recipients of federal funding. Because federal funds were used to pay for patients' use of defendants' products, and because defendants were falsely certifying their compliance with the AKS (due to their quid pro quo scheme with HANJ/HSI), plaintiff contends he has stated valid claims for FCA and AKS violations.

Plaintiff's math (and his corresponding assumption that federal funds are implicated) is too attenuated and derivative to state a viable claim under the heightened Rule 9(b) standard, and even under the regular Rule 8(a) standard. There are no factual allegations to support the conclusion that the remaining 352 HHS patients were under a federal prescription drug program. This data simply fails to demonstrate with the requisite degree of clarity and certainty a connection between defendants' alleged kickback scheme with HANJ/HSI and payments from the federal government.[10]

According to plaintiff, defendants gave charitable contributions to HANJ/HSI so that HANJ/HSI would steer its members to hemophilia treatment centers to prescribe patients with defendants' hemophilia products. Plaintiff claims that this evidences an overall scheme of false certification of compliance

[10] It is unclear whether Plaintiff's allegations concerning gifts provided to Medco patients on Medicare exceeding the maximum dollar amount permitted by the AKS is an allegation of a separate illegal scheme or somehow related to the allegations concerning charitable donations. In any amended pleading, Plaintiff should clarify this point.

with the AKS to secure payment from federal funds. Although there is no doubt that pharmaceutical companies provide gifts to patients and make contributions to charities based, in part, on their ultimate goal to maximize profits, plaintiff here has not pleaded sufficient facts with the requisite particularity to suggest that defendants' actions alleged violate the FCA.

The fact, however, that 352 HHS patients were not privately insured through funding from the kickback scheme alleged leaves open the question of what kind of financial assistance these patients received, especially when considering the high medical costs associated with the treatment of hemophilia. Although this open question is not sufficient to meet the Rule 9(b) pleading requirement to state "with particularity" that the 352 HHS patients must have therefore received federal assistance, the Court will not foreclose plaintiff from filing a third amended complaint should he be able to properly comply with the Rule 9(b) standard to more concretely, rather than through inference, plead that defendants' charitable contributions were intended to, and did, induce referrals of patients receiving federal support to defendants' products.

Accordingly, plaintiff's complaint premised on his contention that defendants' charitable contributions violated the FCA through false compliance with the AKS will be dismissed without prejudice to plaintiff's right to re-file this claim within 30 days, if he

can do so consistent with the Court's direction above.[11]

2. Excessive gifts

Plaintiff also claims that defendants provided Medicare recipients with improper gifts so that they would be favorable to the HTCs' continued prescription of defendants' hemophilia products. To support this claim, plaintiff refers to Exhibit N to his complaint, which is a chart of Medco's hemophilia patients. The chart lists the amount of factor each patient uses, each patient's insurer, and the "gift" provided to them, such as snacks, lunches and dinners. A few of these patients are listed as federal Medicare recipients.

Plaintiff's complaint is unclear how these alleged excessive gifts violate the FCA. In one paragraph of his complaint, plaintiff claims that these gifts exceed the nominal amount permitted under the Civil Monetary Penalty Law, 42 U.S.C. § 1320a-7(a):

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[11]Because the Court will dismiss plaintiff's claims based on defendants' charitable contributions because of plaintiff's pleading deficiencies, it is unnecessary to address defendants' arguments that plaintiff's claims must be dismissed against Medco because of plaintiff's inability to adequately plead any FCA-violative conduct by Medco, separate from Accredo/HHS, or that plaintiff has not pleaded any viable conspiracy. It is important to note that should plaintiff re-file his claims based on defendants' charitable contributions, he must not only comply with Rule 9(b) with regard to pleading how the contributions are tied to federal funds, but he must also comply with Rule 9(b) as to Medco's alleged involvement, as well as to the elements of any alleged conspiracy.

> Defendants, in order to keep the hemophilia patients that have been referred, have also violated the Civil Monetary Penalty provisions of Section 1128A(a)(5) of the Social Security Act, 42 U.S.C. §1320a-7(a) as enacted as part of Health Insurance Portability and Accountability Act of 1996 (HIPAA) by offering and/or providing its hemophilia patients who are Medicare or Medicaid beneficiaries "remuneration" that it "knows or should know is likely to influence the beneficiary's selection of a particular provider." . . . . Defendants' representatives routinely and systematically provide gifts that exceed the permitted limit to keep hemophilia patients receiving specialty pharmaceuticals, which include expensive meals and other gifts. . . . A substantial portion of this cost is borne by Federal Health Care programs. The market place for providers is competitive but also limited. The practices of Medco described herein corrupts this market and results in excess cost to the federal fisc.

(SAC ¶¶ 9, 10, 11.) Later in his complaint, in his three counts for FCA violations, plaintiff claims that these excessive gifts violate the FCA because they were illegal inducements that resulted in false payments by the federal government. (See SAC ¶¶ 115, 116, 117.) Thus, plaintiff's complaint appears to contend that defendants' alleged violation of the CMPL serves as the basis for his FCA claims.

As explained above, a claim is considered false under the FCA when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for government payment. U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 304 (3d Cir. 2011). Defendants point out, however, that a violation of the CMPL cannot serve as the basis for a FCA claim. (See Def. Br. at 12-13.) In his

opposition to defendants' motion to dismiss, plaintiff does not appear to contest this, and clarifies that his FCA claims based on the excessive gifts are predicated not on the CMPL, but rather the AKS.

In his opposition brief, plaintiff contends that defendants maintain billing privileges with Medicare and signed a provider agreement form 855s, wherein defendants agreed that payment by Medicare is conditioned upon compliance with the anti-kickback statute. (Pl. Opp. at 15-16.) Because defendants' gifts are not considered "nominal," and are intended to induce patient use of defendants' hemophilia products, plaintiff claims that these gifts violate the AKS, and the prescriptions stemming from the illegal gifts result in payments by the federal government in violation of the FCA. In other words, plaintiff claims that defendants are paid by Medicare for the prescriptions procured by illegal kickbacks to Medicare patients. This articulation of plaintiff's FCA claims based on excessive gifts is not so precisely stated in his complaint.

Plaintiff's complaint demonstrates that defendants give certain non-nominal gifts to patients whose prescriptions are paid for by Medicare. The deficiency in his claim is that this fact alone is not sufficient under Rule 9(b) to make the leap that the gifts are violations of the AKS, and that defendants expressly and falsely certified compliance with AKS when they received payment

from federal funds for prescriptions resulting from those illegal gifts. Plaintiff's opposition brief does a better job of substantiating his FCA claims based on the excessive gifts, but his brief cannot cure the pleading deficiencies in his complaint.

Thus, as with his claims based on defendants' charitable contributions, plaintiff's FCA claims based on illegal gifts to patients must be dismissed. The Court, however, will provide plaintiff with 30 days to re-file these claims should he be able to do so consistent with Rule 9(b).[12]

CONCLUSION

For the reasons expressed above, defendants' motion to dismiss plaintiff's claims arising under federal law will be granted. Because plaintiff's federal claims are dismissed, and because this case is still at the pleading stage, the Court declines to exercise supplemental jurisdiction over his state law claims. See 28 U.S.C. § 1367(c)(3) (providing that a district court may decline to exercise supplemental jurisdiction over state law claims when it "has dismissed all claims over which it has original jurisdiction"); Elkadrawy v. Vanguard Group, Inc., 584 F.3d 169, 174 (3d Cir. 2009) (affirming district court's dismissing state law claims after federal claims were dismissed). Accordingly,

[12]See note 11 with regard to plaintiff's conspiracy claims and his claims against Medco should he choose to file a third amended complaint.

plaintiff's state law claims are also dismissed.[13] Plaintiff, however, is provided 30 days to re-file his claims in a third amended complaint should he be able to do so consistent with the direction provided by the Court herein.

An appropriate Order will be entered.

Date: December 30, 2013 — s/ Noel L. Hillman

At Camden, New Jersey — NOEL L. HILLMAN, U.S.D.J.

[13] If plaintiff chooses to file a third amended complaint, it is also his choice as to whether to pursue his claims based on state law.